REMARKS

Claims 1-40 are pending in the application. Claims 23-40 are withdrawn from consideration. Claims 1-22 are rejected. Claims 1, 3-5, 9, 12, 14, 17, and 19-20 are hereby amended. Support for the amendments is found on page 8, lines 4-19, page 11, lines 24-30, and page 12, lines 1-9. The amendments do not constitute new matter. In consideration of the amendments and the following remarks, reconsideration of claims 1-22 is respectfully requested.

Claim Rejections - 35 USC § 112, second paragraph

Claims 1-22 are rejected under 35 U.S.C §112, second paragraph, as being indefinite. The Patent Office stated that in claim 1, it is unclear what is encompassed by low in "low birefringent glass". The term "low birefringent" or "low birefringence" is a commonly used term of art which describes a substance that minimally refracts an unpolarized light ray into two separate, orthogonally polarized light rays. Because of this property, low birefringent materials are suitable for optic sensing applications, even though they are not entirely nonbirefringent. The term of art "low birefringence" may describe a plethora of substances including, but not limited to, glass, minerals, fibers for optic devices, and organic polymer materials such as silsesquioxane. (See Pottiez et al. 2004. *Optics Communications;* 229:147–159 and Hasui et al. 2004. *Jpn. J. Appl. Phys.*; 43(4B): 2341-2345.) Additional examples can also be provided upon request.) In the present invention, the detection chamber of the assay cassette is delineated on at least two sides by "low birefringent glass" such that the low birefringent background of the glass walls of the detection chamber do not interfere with the polarized light that is directed through the walls of the detection chamber.

Claim 1 has been amended for clarity and to address the Patent Office's comment regarding antecedent basis. It is believed that the amendments to claim 1 overcome the Section 112 rejections.

In response to the Examiner's comments, Claim 3 has been amended to recite "wherein the flow channel comprises in series, an inlet port, a first conduit connecting the inlet port and the mixing chamber closest to the first end, one or more mixing chambers, a second conduit connecting the mixing chamber closest to the second end and the detection chamber, and the detection chamber."

Claim 4 has also been amended, and now recites "the device according to claim 1, wherein the flow channel comprises two or more mixing chambers arranged in series, wherein the mixing chamber closest to the first end is in fluid communication with the inlet port, and wherein the mixing chamber closest to the second end in the series is in fluid communication with the detection chamber."

Claim 5 has been amended to recite "the device according to claim 4, wherein the flow channel comprises two or more conduits, wherein each conduit is situated between two elements of the flow channel and is in fluid communication with the elements, and wherein the elements are selected from an inlet port, one or more mixing chambers, and a detection chamber."

Claim 9 now recites "a conduit situated between the mixing chamber closest to the second end and the detection chamber, wherein said conduit induces laminar flow when the device is in use."

Claim 12 has been amended to recite "wherein one or both of the low or non birefringent glass walls located in the detection chamber has longitudinal microgrooves oriented along the axis of the cassette that bisects the first and second ends of the cassette."

Claim 14 has been amended to recite "wherein the pattern of the flow of fluid between the inlet port and the one or more mixing chambers, recited in claim 1, is substantially turbulent, and wherein the pattern of the flow of fluid between the mixing chamber closest to the second end and the detection chamber is substantially laminar."

Claim 17 has been amended to recite "a system for detecting the presence of a ligand in a sample, comprising: (a) at least one assay cassette, according to claim 1; and (b) a flow directing device in communication with the assay cassette."

Finally, claims 19 and 20 have been amended to clarify how the filter and reader are in communication with the detection chamber.

Claim Rejections - 35 USC §103

1. Claims 1-6, 9-11 and 13-20 are rejected under 35 USC § 103(a) as being unpatentable over Kellogg et al., US Pat. No. 6,302,134 (hereinafter "Kellogg") in view of Hajduk et al., US Pat. No. 6,836,326 (hereinafter "Hajduk").

The Patent Office stated that Kellogg teaches a device which comprises a flow channel

comprising "at least one mixing chamber and a detection chamber in fluid communication with the one or more mixing chambers . . . wherein the detection chamber is located at the second end of the cassette." The Patent Office also stated that the Kellogg reference teaches that "the one or more mixing chambers and detection chamber define a substantially linear flow path from the first end to the second end of the cassette." The Patent Office correctly noted that Kellogg fails to teach a detection chamber comprising low or nonbirefringent glass, but states that such a detection chamber is taught by Hadjuk.

In order to establish obviousness of a claim, "all the claim limitations must be taught or suggested by the prior art." (MPEP §2143.03). Neither Kellogg nor Hadjuk, alone or combined, teach several of the features of claim 1, as amended. Claim 1 recites assay components comprising a) "a receptor that exhibits specificity for a ligand", b) "a microparticle that exhibits specificity for the receptor", c) "a liquid crystalline material", and d) "a detection chamber that provides for the detection of distortion in the liquid crystalline material." There is no mention in the Kellogg reference of "a receptor that exhibits specificity for a ligand", "a microparticle that exhibits specificity for the receptor", a "liquid crystalline material" or "a detection chamber that provides for the detection of distortion in the liquid crystalline material." Because Kellogg is not in any way concerned with detection in liquid crystalline substances, one of ordinary skill in the art would not be motivated to combine Kellogg with Hajduk. Even when combined, Hadjuk does not provide all that Kellogg lacks, notably "a receptor that exhibits specificity for a ligand" or "a microparticle that exhibits specificity for the receptor." Because all of the features of claim 1, as amended, are not taught or suggested by the combination of the Kellogg and Hadjuk references, these references do not render claim 1 obvious under 35 USC §103. Claims 2-8, 9-12, and 13-20 depend on claim 1, and therefore are also not obvious (*see* MPEP §2143.03, stating that, "if an independent claim is nonobvious under 35 USC §103, then any claim depending therefrom is nonobvious.").

2. Claims 1, 17, 21 and 22 are rejected under 35 USC § 103(a) as being unpatentable over Christian, US Pat. No. 4,673,657 (hereinafter "Christian") in view of Hajduk.

The Patent Office has stated that Christian teaches "at least one mixing chamber and a detection chamber in fluid communication with the one or more mixing chambers . . . wherein the detection chamber is located at the second end of the cassette" and that "the one or more

mixing chambers and detection chamber define a substantially linear flow path from the first end to the second end of the cassette." Again, the Patent Office has stated that Hadjuk teaches a detection chamber comprising low or nonbirefringent glass.

Because Christian does not express any concern for detection in a liquid crystalline material, there would not be a motivation to combine Christian with Hadjuk. If combined, however, Christian and Hadjuk also do not teach or suggest all the features of claim 1, as amended. In particular, the combination does not teach "a microparticle that exhibits specificity for the receptor." Nowhere in either Christian or Hadjuk is there any mention of this feature. Because all of the features of claim 1, as amended, are not taught by the combination of the Christian and Hadjuk references, claim 1 is not obvious under 35 USC §103. Because claims 17, 21 and 22 depend from claim 1, they are also not obvious.

3. Claims 7 and 8 are rejected under 35 USC §103(a) as being unpatentable over Kellogg in view of Steams, US Pat. No. 2,645,463 (hereinafter "Stearns").

It has been argued in sections 1 and 2 above that amended claim 1 is not rendered obvious by either the combination of Kellogg and Hadjuk or the combination of Christian and Hadjuk. Because claims 7 and 8 depend from claim 1, they are also nonobvious. While the Patent Office has stated that Steams teaches "structures that induce turbulent flow," the combination of Kellogg and Steams still does not teach all of the features of claims 7 and 8, as they depend upon amended claim 1. Accordingly, claims 7 and 8 are not obvious under 35 USC §103(a). Moreover, Steams makes no mention of "a receptor that exhibits specificity for a ligand", "a microparticle that exhibits specificity for the receptor", a "liquid crystalline material" or "a detection chamber that provides for the detection of distortion in the liquid crystalline material."

4. Claim 12 is rejected under 35 USC §103(a) as being unpatentable over Kellogg in view of Hajduk, and further in view of Murphy, et al., US Pat. No. 5,864,641 (hereinafter "Murphy").

The Patent Office has stated that Murphy teaches "microgrooves in the nonbirefringent glass" as recited in claim 12. However, as argued in section 1, amended claim 1 is not rendered obvious by the combination of the Kellogg and Hadjuk references. Because claim 12 depends from claim 1, it is similarly nonobvious. Furthermore, there would not be a motivation to

combine Kellogg with Murphy, because Kellogg does not make any mention of optical sensing whatsoever. Even if combined, Murphy does not provide what Kellogg and Hadjuk lack, in that it does not mention or suggest "a receptor that exhibits specificity for a ligand", "a microparticle that exhibits specificity for the receptor", a "liquid crystalline material" or "a detection chamber that provides for the detection of distortion in the liquid crystalline material." Therefore, claim 12 is not obvious under 35 USC §103(a).

Applicant contends that claims 1-22, as amended, are not rendered obvious by any combination of references cited by Examiner. Thus, applicant contends that claims 1-22 are in condition for allowance. Prompt notice of such allowance is respectfully requested.

This amendment is filed with a petition for extension of time of two months, in duplicate, and authorization to charge our deposit account for the required fee. Should any other fees be due in this case, or any further extensions of time be required, Applicant hereby requests such extensions and grants the Commissioner authorization to charge such fees, and to credit any overpayments to deposit account 03-0172.

Respectfully submitted,

Date: 10/17/05

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